

Remarks/Arguments

The foregoing amendments in the claims are of formal nature, and do not add new matter.

Claims 39-43 are presently pending in this application and have been rejected on various grounds. These rejections are respectfully traversed.

IDS

The Examiner indicates that he located the IDS filed 4-11-02 and has considered those references instead of those filed in the supplemental IDS. Applicants have made a note of this.

Claim Rejections - 35 USC § 101

Claims 39-43 remain rejected under 35 U.S.C. §101 for lack of utility. The Examiner asserts that he "cannot determine the *degree* to which PRO302 had any effect on vascular permeabilization....making it difficult to determine just how effective PRO302 is at inducing permeability". The Examiner adds that "the mere fact that PRO302 may have an effect on vascular permeabilization is not sufficient grounds for one of skill in the art to assume that it can be used in wound healing and/or diagnosis of a particular disease or condition" and that "the skilled artisan would conclude that the invention lacks specific or substantial utility". Applicants respectfully traverse the rejection.

Applicants present supportive evidence (Exhibit A and B) to show "how effective PRO302 is at inducing permeability." When representative polypeptides like PRO302 (referred to here as BKN or Bolekine) are injected intra-dermally into a guinea pig concurrent with the injection of the Evan's blue dye intra-cardially (Exhibit A), patches of leaked Evans blue dye appear at the site of injection of PRO302 due to vascular leak. The results of a representative experiment is shown in Exhibit B: showing results with saline control, 1 µg VEGF (positive control), test samples -2 different lots of a representative test polypeptide and 10 µg IL-8 (negative control). As evidenced by these results, it is very easy to monitor the ability of polypeptides like PRO302 to induce vascular leakage compared to a negative and a positive control.

Further addressing utility, Applicants submit that based on the results of the vascular leak

assay, one skilled in the art would know to use anti-PRO302 antagonists (antibodies) to stop vascular leakage, for example, in pulmonary leakage, capillary leakage, tumor leakage, or in burns. Such uses are substantial, credible and specific and would be clearly evident to a person skilled in the art. In explaining the "substantial utility" standard, the M.P.E.P. 2107.01 cautions that Office personnel must be careful not to interpret the phrase "immediate benefit to the public" or similar formulations used in certain court decisions to mean that products or services based on the claimed invention must be "currently available" to the public in order to satisfy the utility requirement. "**Rather, any reasonable use that an applicant has identified** for the invention that can be viewed as providing a public benefit **should be accepted as sufficient**, at least with regard to defining a "substantial" utility." (M.P.E.P. 2107.01, emphasis added.) Indeed, the Guidelines for Examination of Applications for Compliance With the Utility Requirement, set forth in M.P.E.P. 2107 II (B) (1) gives the following instruction to patent examiners: "If the applicant has asserted that the claimed invention is useful for any particular practical purpose . . . **and the assertion would be considered credible by a person of ordinary skill in the art**, do not impose a rejection based on lack of utility (emphasis added)."

Accordingly, the Examiner is respectfully requested to reconsider and withdraw the present rejection.

Claim Rejections- 35 U.S.C. §112, second paragraph

Claim 39-43 are rejected under 35 U.S.C. §112, second paragraph, allegedly for being vague and indefinite in defining the term "specifically binds to."

Without acquiescing to the rejection, Applicants have deleted the term "specifically" in claim 39 to obviate this rejection. Accordingly, the present rejection should be withdrawn.

The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney Docket No.: 39780-1618P2C40).

Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

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